Special 510(k) Premarket Notification Submission: Summary of Safety and Effectiveness

Date of Preparation: September 19th, 2006

OCT - 5 2006

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Device Information:

Trade Names: **Pajunks HF Electrodes**

Common Name: **Monopolar Electrodes**

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Reference: 21 CFR 878.4400, April 1. 2005

Poposed Classification: Regulatory Class: II

Proposed Product Code: GEI

Predicate Devices:

1. Pajunks monopolar Ceramic Tip electrodes **K053282**
2. Pajunks Modular valve handles for adaptable tubes **K011997**
3. Pajunks monopolar electrodes marketed under **K033249**

Device Description:

Pajunks MIS-Instruments and HF-electrodes are used during minimal invasive surgery, according to the professional surgeon and the instructions for use.

The Pajunk adaptable and retractable HF electrodes are multiple uses, non-sterile delivered and latex free medical devices. They are intended for transient delivery of energy required for coagulation of tissue.

The modular system for optional monopolar coagulation enables a surgeon to manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures. The instruments are insulated for optional monopolar coagulation.

The Pajunk MIS-System contains but is not limited to HF-electrodes for comfortable and safe coagulation with and without suction/ irrigation and microsurgical instruments with and without suction/irrigation.

Pajunk provides electrodes with and without suction and irrigation element and electrodes with suction and irrigation capacity with retractable/ extendable tips. Tubes for suction/irrigation are available seperately also.

Pajunks electrodes consist of a stainless steel guidance rod, insulated tube, ceramic or polyamide insulation at tip and stainless steel electrode tip for coagulation. Isolation at tip is made by ceramic or poly amid and already cleared for market.

The electrodes are fixed to handle via click-screw, Luer or Pajunks M8x1 connector.

Pajunks electrode and instrument series are modular and interchangeable as stated in the user instructions. Disposable inserts are also available.

Substantial equivalenve: basis for submission

The subject of Pajunks **K011997** are Pajunks multipurpose handles (Modular valve handles) already designed for use with the HF Electrodes subject of this submission.

In **K033249** FDA cleared HF Electrodes and instruments for *either* coagulation, grasping and so on *or* suction/irriragtion (channel only). The subject of this PMN is the combination of both: HF Electrodes within a suction/irrigation channel and optional retraction-extension.

There are no changes in material or technique in fact; **the subject of this PMN is a combination of techniques already cleared in the predicates**. Pajunks HF electrodes subject of this PMN optionally are for suction/irrigation and coagulation *at the same time* with the same electrode enabled by retraction-extension feature.

The electrode can be drawn back into the tube – re-tracted – for suction/irrigation procedures. Afterwards it can be comfortably extended to go on coagulating (or whatever the surgical intervention is intended to).

The combination of this two cleared technologies does increase safety and comfortability of the procedure because it shortens the time period the surgical intervention takes place. Insttead of employing two different instruments or an instrument inside a working channel The retractable electrode combine both, suction/irrigation and surgical intervention.

Pajunk's adaptable and retractable HF electrodes are substantially equivalent to Pajunk's monopolar electrodes marketed under 510(k) number **K033249**. All materials, dimensions, fixation specifications and intended use are identical. A retraction/extension feature has been added.

Pajunk's monopolar adaptable and retractable HF electrodes are equivalent in design, physical dimensions, metal and plastics materials, to Pajunks monopolar ceramic/ polyamid tip electrodes marketed under 510(k) number **K053282, K033249** and are intended to be used with Pajunks Modular Valve handle system with different interchangeble fixation methods (click-screw, Luer, M8x1) cleared for market under **K011997**.

Technological Equivalence

	Predicate device K033249, K053282	**Subject device K062047**	**Predicate device K011997**
Shape of electrode tip tip	grasping forceps, biopsy, clamps and scissors, hook, right-angle, spatula, knife, 45°, needle	**Retractable/ extendable:** hook, right-angle, spatula, knife. 45°, needle **Suction/ Irrigation:** grasping forceps, biopsy, clamps and scissors, hook, right-angle, spatula, knife, 45°, needle	Not applicable
Connector	M8 x 1 or Luer or click-screw	M8 x 1 or Luer or click-screw	M8 x 1 or Luer or click-screw
Features	Coagulation Suction/ irrigation	Suction/ Irrigation Coagulation Retraction/ Extension	Suction/ Irrigation Coagulation

Sterilization

Pajunks HF Electrodes are supplied non-sterile. They have to be sterilized before initial use and before each further use. They can be sterilized up to five times (validation report in sect. 14 of this submission).

Biocompatibility

Biocompatibility information for Pajunk's adaptable and retractable HF is located in Section 15.0 of this submission.

Indications for use

Pajunks HF Electrodes are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Conclusion:

The comparison between the predicate devices and the proposed device demonstrates that the proposed Pajunk devices are at least as safe and effective and substantially equivalent to Pajunks predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

Pajunk GmbH
% Mr. Christian Quass
Director Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen
Germany

Re: K062047
Trade/Device Name: **Pajunks HF Electrodes**
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 25, 2006
Received: September 27, 2006

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

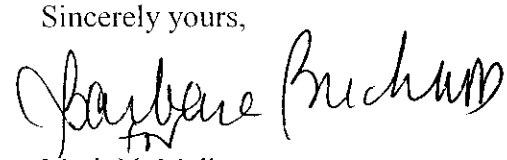
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PAJUNK®
MEDIZINTECHNOLOGIE

Indications for use

510(k) Number: K062047

Device Name: Pajunks HF Electrodes

Indications for Use:

Pajunks HF Electrodes are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062047